UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,202	12/01/2003	Richard M. Batch	61616	3293

24201 7590 05/01/2006

FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
HOPKINS, CHRISTINE D	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,202	BATCH, RICHARD M.	
	Examiner	Art Unit	
	Christine D. Hopkins	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1 December 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The specification exceeds 20 pages.

Claim Objections

2. Claims 7 and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Claim 7, which states, "wherein the processor is further configured to determine a medical treatment guideline representing acceptable values for the selected parameter in accordance with the analysis," does not further limit the subject matter of claim 1. Any structure capable of performing the limitations set forth in claim 1 is capable of performing that of claim 7. Claim 18, which recites "determining a medical treatment guideline representing acceptable values for the selected parameter" does not further limit the claimed subject matter of claim 12. The third element of claim 12 is also directed towards "determining a medical treatment guideline representing acceptable values for the selected treatment parameter."

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Coutre (U.S. Patent No. 5,317,506). Coutre discloses an infusion management and pumping system whereby infusion prescriptions of patients are generated and monitored by a pharmacy management system. In reference to claim 1, the system of Coutre comprises a memory, element 20-3 of Fig. 1 that contains individualized infusion data (i.e., medical treatment parameters) for every patient within the pharmacy management system, element 20. Also, refer to col. 5, lines 20-33. With respect to the processor of claim 1, processing of the infusion data, or medical treatment parameters, to include such details as volume per dose, time per dose and dose frequency, results in subsequent label generation that will be affixed to the drug solution later administered to the patient (see col. 6, lines 32-55 and col. 7, lines 18-24).

Claim 2, which recites "wherein the analysis includes providing a distribution of the treatment parameter values," does not set forth a structure which further limits the subject matter of claim 1 which it forms its dependency on; any structure capable of performing the limitations set forth in claim 1 is capable of performing that of claim 2. In regards to the "distribution of treatment parameter values" of claim 2, Coutre teaches an infusion pumping system which issue a prompt, a "beep," to verify whether or not data

read from the infusion bar code label falls within expected ranges for a particular patient, thus analyzing a specific distribution (see col. 10, lines 2-8).

In reference to claim 3, Coutre discloses a database for storing infusion data (see elements 38-4 and 40-4 of Fig. 1) which will be used to compare the data on a bar code read from the patient's chart, the infusion solution, and that which was originally specified for a particular patient in pharmacy management. If a mismatch occurs, the system provides an indication, such as a "beep" (see col. 10, lines 15-28) to indicate the deviation from "acceptable values".

With respect to claim 4, the data stored in the database of Coutre may be edited to change a particular drug regimen according to, for instance, any allergic reactions that may occur as a result of infusion of two particular drugs. This mismatch will signal the administrator of such an occurrence whereby s/he may edit the data to adjust the regimen as a result of the comparison (see col. 10, lines 35-49). Additionally, "a report" as recited in claim 5, is maintained in the form of an "I.V. history" for each course of infusion therapy and may thus be generated in the form of a printed output to a local printer for subsequent attachment to a patient's chart, as taught by Coutre (see col. 10, lines 47-49 and col. 14, lines 17-20). With respect to claim 6, a "report" is generated of the analysis of Coutre in the form of a barcode label, containing all of the infusion data, which is affixed to the infusion solution to be later administered to the patient (see col. 6, lines 53-56).

In view of claim 7, the system of Coutre performs a validity check on the data of the infusion solution to ensure that it falls within an expected range of acceptable

values. If the check determines otherwise, the system will respond in a manner distinguishable from a "good beep" (see col. 10, lines 5-10). In reference to claim 8, Coutre teaches an infusion system capable of generating a record of patient and infusion data (see cols. 12 and 13, lines 66-67 and 1-8), and recording this data and transferring it directly to the pharmacy management system where it is stored into memory (see col. 14, lines 37-39).

With respect to claim 9, any report generated by the system of Coutre is capable of determining an optimum regimen value as evidenced by the beep or alarm which is sounded by virtue of being within or outside of a predetermined range of infusion data. Furthermore, claim 9 does not provide for a specific "optimum value" as depicted in Fig. 9.

In view of claim 10, Coutre discloses a system that incorporates patient sensors to process information such as blood pressure and glucose levels (i.e., physiological data), which in turn send this to the infusion system to alter the planned program in response to the sensed information. Thus, a suitable treatment measure is taken to account for any alterations in physiological data observed by the patient sensors (see col. 4, lines 16-21).

In accordance with claim 11, the system of Coutre includes many infusion pumping systems (i.e. medication administration devices), one associated with a particular patient in the hospital (see col. 3, lines 67-68 and col. 4, lines 1-5); the infusion pumping system to include a database memory (see col. 10, lines 15-16) that includes patient data information, and medication information such as allergies to

prescribed drugs (col. 10, lines 25-39). With respect to the "central processor" recited in claim 11, the data received from the individual infusion systems of Coutre can be transferred to the pharmacy management system where it is stored in memory and can be processed further for analysis of medication usage (see col. 14, lines 36-41). Furthermore, in reference to the "database" of claim 11, the database of Coutre is located in the pharmacy management system, and includes a drug database which will alert an administrator of incompatible drugs, thus representing "optimal values" for the operation of the medical administration device, or infusion pump in the instance of Coutre (see col. 2, lines 16-19). Coutre also teaches an interface by which to transfer information to the "central processor", (i.e., hospital administration system or pharmacy management system) via a serial port and multiplexer or manual transfer (see col. 14, lines 29-39). In addition, the "processor configured to compile the medical treatment data" of claim 11 is in accordance with that disclosed by Coutre. The stored infusion parameters can be selected by an administrator in the analysis, by considering a number of elements such as: total drug usage, total patient drug usage, drug concentration, etc. (see col. 14, lines 37-47) selected from and run on the pharmacy management and hospital administration databases (elements 20-3 and 26-3 of Fig. 1, respectively).

With respect to claim 12, one particular embodiment of Coutre teaches a remote feedback network computer which functions as a remote controller for a network of pumping systems (from a plurality of patients); each pumping system containing medical data for a particular patient such as the IV history as noted above in claim 5

(see col. 14, lines 60-66). As further suggested by Coutre, an administrator or operator at the remote computer can review all alarm conditions, thus indicating that a particular treatment value must be assigned to a particular patient in order to warrant an alarm (col. 14, line 68 and col. 15, lines 1-3). In accordance with the elements of "compiling the medical treatment data" and "analyzing the treatment parameter values" as recited in claim 12, the remote computer as mentioned above evaluates data taken from sensors or the infusion system and according to a preprogrammed set of conditions, determines if the infusion regimen should be changed as a result of the sensed conditions (see col. 15, lines 18-26). If the analysis determines a change is necessary, this implies that the treatment has fallen outside of the "acceptable values" and thus suggests an appropriate change to the operator (see col. 15, lines 26-28).

With respect to claim 13, a "distribution" is provided for by Coutre such that a "beep" or other distinguishable sound is made if the data read by the bar code reader falls outside of an expected range, or distribution for a particular patient's treatment regimen (see col. 10, lines 2-11).

In regards to claim 14, Coutre discloses that the data containing relevant medication administration stored in the database of the infusion pumping system and according to which drug is selected to be administered to the patient, the system will automatically check this against the drugs prerecorded in the database for any discrepancies, i.e., a drug to which a patient may display an allergic reaction (see col. 10, lines 36-41). Furthermore, with reference to claim 15, if the infusion system taught by Coutre should sense a mismatch in the drug treatment parameter according to those

stored in the database, the system will prompt the user of the mismatch whereby the user may edit this data to reflect the change in the treatment regimen, thus entering this new treatment regimen into the database (see col. 10, lines 39-49). In view of claim 16, the system of Coutre may generate a report of the above-mentioned comparison in the form of a printed output to a local computer to be attached to, or "updated" on a patient's chart (see col. 10, lines 47-49 and col. 14, lines 17-21).

In accordance with claim 17, Coutre discloses the generation of a report (i.e., a printed barcode label) containing all of the infusion data associated with the medication to be delivered, which can be affixed to the infusion solution for subsequent administration to the patient (see col. 6, lines 53-56).

With respect to claim 18, Coutre teaches the performance of a validity check on the data of the infusion solution by way of a bar code reader to ensure that the information encoded in the label of the infusion solution falls within an expected range of acceptable values. If the check determines otherwise, the infusion pumping system will respond in a manner distinguishable from a "good beep" (see col. 10, lines 5-10).

In reference to claim 19, Coutre teaches an infusion system capable of generating a record of patient and infusion data (see cols. 12 and 13, lines 66-67 and 1-8), and recording this data and transferring it directly to the pharmacy management system where it is stored into memory (see col. 14, lines 37-39), thus integrating the data into a database for future retrieval.

In view of claim 20, any "report" generated by the teachings of Coutre (i.e., display on a monitor or printed version) is capable of determining an optimum regimen

value as evidenced by the beep or alarm which is sounded by virtue of being within or outside of a predetermined range of infusion data. Moreover, claim 20 does not provide for a specific "optimum value" as depicted in Fig. 9.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,781,442 to Engleson discloses an automated hospital care management system that monitors care to the patients, one particular feature providing an alarm when an infusion exceeds a predetermined length of time.

U.S. Patent No. 6,024,699 to Surwit discloses systems and methods for monitoring and treating patients using a central data processing system capable of communicating with individual patient monitoring systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christine D Hopkins
Examiner
Art Unit 3735
4/28/06

CDH

Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735